

## **REMARKS**

### **Formal Matters**

Claims 55-60 and 62-69 were examined. Claims 1-54 were previously canceled. **Claim 61 was missing in the originally filed claims due to misnumbering.** Claims 63 and 64 were allowed. The Applicants thank the Examiner for the indication of allowance. Claims 55, 56, 58, 65 and 67-69 were rejected. Claims 57, 59-62 and 66 were objected to. The Applicants thank the Examiner for the indication of allowability of claims 57, 59-62 and 66 if re-written in independent form including all of the limitations of the base claims and any intervening claims. The Applicants also thank the Examiner for the indication of allowability of claims 67-69 if re-written to overcome the rejections under 35 U.S.C. 112, second paragraph and to include all of the limitations of the base claims and any intervening claims.

Claims 70-72 are added as new. Support for these amendments may be found throughout the specification and originally filed claims, e.g., paragraphs [0033], [0037], [0045] and [0046].

Claims 65, 67 and 68 are amended for consistency with the claims from which they depend.

The specification has been amended to update the status of the parent case.

As no new matter has been added, the Applicants respectfully request the entry of the amendments.

### **Objections to the Specification**

The specification is objected to because the status of the parent case is not updated. The specification is been amended as suggested by the Examiner to specify the status of the parent case. Accordingly, the Applicants respectfully request that this objection be withdrawn.

### **Rejections Under §112, ¶2**

Claims 65, 67-69 are rejected under 35 U.S.C. §112, second paragraph. Claim 65 is amended to replace “beads” with “barrier” which is specified in claim 58 from which claim 65 depends. Claim 67, and claim 69 which depends from claim 67, are amended to remove reference to plasma. Claim 68 is amended to remove reference to “of said particles, said solution of said calcium ions, and said plasma”. Accordingly, the Applicants respectfully request that this objection be withdrawn.

**Rejections Under 35 U.S.C. §103(A)**

Claims 55-56, 58 and 65 are rejected under 35 U.S.C. §103(a) as being unpatentable over Sanz in view of Bull. The Applicants respectfully traverse this rejection.

Sanz is directed to a coagulometer capsule that includes two enclosures E1 and E2. E1 includes a blood coagulation factor in a solution of blood anti-coagulant. Sanz specifically teaches thromboplastine as the coagulation factor and trisodium citrate or sodium oxalate as the anti-coagulant. E2 includes a calcium chloride solution.

Sanz specifically teaches the use of a **blood coagulation factor**. It is important to note that blood coagulation factors are specific components present in the blood whose actions are essential for blood coagulation and, as Sanz describes, are conventionally designated by Roman numerals I, II, II, etc. In other words, as Sanz makes clear, the term “blood coagulation factor” has a specific meaning in the art and does not include any substance that causes blood to coagulate. Sanz specifically describes these coagulation factors and even describes thromboplastine as a tissue extract of a kind corresponding to factor III of the blood (see for example col. 1 and col. 3, lines 59-66). In fact, the coagulometer of Sanz is taught as specifically suitable with the combination of thromboplastine as the coagulation factor and trisodium citrate or sodium oxalate as the anti-coagulant as Sanz teaches that trisodium citrate and sodium oxalate are excellent thromboplastine stabilizers which enables the device that includes the combination of components to be stored for relatively long periods of time at low temperatures (see col. 4, lines 15-23). Accordingly, Sanz does not teach or suggest that the blood coagulation factor in the first compartment can be anything that initiates clotting, as asserted by the Examiner. Instead, Sanz specifically teaches that the first compartment includes a blood coagulation factor as known in the art, and more specifically teaches thromboplastine as the blood coagulation factor.

The Examiner refers to Fig. 8 of Bull and specifically refers to the diatomaceous earth or ground glass 48 and characterizes them as plasma aggregatable particles and asserts that it would have been obvious to one of skill in the art to modify Sanz to use the diatomaceous earth or ground glass of Bull instead of the blood coagulation factor taught in Sanz.

First and foremost, the Applicants submit that the diatomaceous earth or ground glass of Bull are not analogous to the plasma aggregatable particles of the subject invention, nor are they blood coagulation factors.

Furthermore, Sanz requires the use of anti-coagulants, yet Bull specifically teaches that anti-coagulants are not used (see for example col. 2, lines 32-36 and 64-68) and instead Bull teaches the use of a nonthrombogenic coating agent such as an ionic radiographic contrast agent. In fact, Bull specifically teaches that an object of the invention is to alleviate the necessity of adding anti-coagulants and then reversing their effects prior to testing. However, this is exactly the way in which Sanz works. In order to combine the references as suggested by the Examiner, one would have to selectively pick and choose certain teachings of Bull, e.g., the use of diatomaceous earth or ground glass, while selectively disregarding other teachings such as the specific omission of anti-coagulants. However, there is no motivation to selectively choose certain features of Bull while selectively disregarding others.

Still further, assuming arguendo that motivation is found for the selective picking, choosing and omitting of certain features of Bull, there is still no motivation to modify Sanz to replace the blood coagulation factor, and specifically the thromboplastine as taught by Sanz, with the diatomaceous earth or ground glass of Bull, since Sanz specifically teaches the use of blood coagulation factors and more specifically teaches the use of thromboplastine as the blood coagulation factor, and in view of the teachings of Sanz with respect to the important advantages of using thromboplastine, namely that trisodium citrate and sodium oxalate are excellent thromboplastine stabilizers, thereby producing a solution that can be stored for relatively long periods of time at relatively low temperatures.

Accordingly, for at least the reasons described above, claims 55-56, 58 and 65 are patentable over Sanz in view of Bull. As such, the Applicants respectfully request that this rejection be withdrawn.


### **Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-043DIV.

Respectfully submitted,  
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Date: 01/19/05

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